UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

In re ASTRAZENECA PLC SECURITIES LITIGATION	Case No.: 1:21-cv-00722-JPO

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS THE AMENDED COMPLAINT

FRESHFIELDS BRUCKHAUS DERINGER US LLP
Meredith Kotler
Mary Eaton
Marques S. Tracy
Adam M. Rosenfeld
601 Lexington Avenue, 31st Floor
New York, NY 10022
Tel. (212) 277-4000

Attorneys for Defendants

September 27, 2021

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Statutes

TABLE OF ABBREVIATIONS

¶	Paragraphs of the AC
AC	Amended Complaint for Violations of the Federal Securities Laws, filed July 12, 2021 (ECF No. 42)
ADS	American Depositary Share
Alexion	Alexion Pharmaceuticals, Inc.
Annex A	Annex A to this Memorandum of Law
Annex B	Annex B to this Memorandum of Law
AZ	Defendant AstraZeneca plc
AZD1222	A recombinant adenovirus COVID-19 vaccine developed by Oxford and AZ, previously known as "ChAdOx1 nCoV-19," subsequently referred to as "COVID-19 Vaccine AstraZeneca," and now known as "Vaxzevria"
AZD7442	A combination of two long-acting antibodies derived from convalescent patients after SARS-CoV-2 infection
BARDA	Biomedical Advanced Research and Development Authority
BLA	Biologics License Application
CEO	Chief Executive Officer
CEPI	Coalition for Epidemic Preparedness Innovations
CFO	Chief Financial Officer
CHMP	EMA's Committee for Medicinal Products for Human Use
CMA	Conditional Marketing Authorisation
CMO	Chief Medical Officer
COV001	Oxford-led Phase I/II clinical trial in the UK for AZD1222
COV002	Oxford-led Phase II/III clinical trial in the UK for AZD1222
COV003	Oxford-led Phase III clinical trial in Brazil for AZD1222
COV005	Oxford-led Phase I/II clinical trial in South Africa for AZD1222

COVAX	COVID-19 Vaccines Global Access, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator
COVID-19	Coronavirus disease 2019, an infectious disease caused by the SARS-CoV-2 virus
CP	Putative Class Period, June 15, 2020 through January 29, 2021, inclusive, as defined in ¶ 1
CVRM	Cardiovascular, Renal and Metabolism
CW	Confidential Witness
D8110C00001	AZ-led Phase III clinical trial in the US for AZD1222
Defendants	AZ, Mr. Soriot, Mr. Dunoyer, and Dr. Pangalos
Dr. Pangalos	Defendant Dr. Menelas Pangalos
DSM	Data and Safety Monitoring
DSMB	Data and Safety Monitoring Board
EC	European Commission
EMA	European Medicines Agency
EU	European Union
EUA	Emergency Use Authorization
EUL	Emergency Use Listing
Ex.	Exhibit to the Tracy Declaration
Exchange Act	Securities Exchange Act of 1934, 15 U.S.C. § 78a *et seq.*
FDA	US Food and Drug Administration
FLS	Forward-looking statement
Form 6-K or 6-K	Report of Foreign Issuer, filed with the SEC, pursuant to Rule 13a-16 or 15d-16 under the Exchange Act
Gavi	Gavi, the Vaccine Alliance
Guggenheim	Guggenheim Securities, LLC

Individual Defendants	Mr. Soriot, Mr. Dunoyer, and Dr. Pangalos
IVA	Inclusive Vaccines Alliance
J&J	Johnson & Johnson
LD/SD	Low dose/standard dose
MHRA	UK Medicines and Healthcare products Regulatory Agency
Mr. Dunoyer	Defendant Marc Dunoyer
Mr. Soriot	Defendant Pascal Soriot
mRNA	Messenger ribonucleic acid
Oxford	University of Oxford, including the Jenner Institute and the Oxford Vaccine Group
Plaintiffs	Lead Plaintiffs Nuggehalli Balmukund Nandkumar and Wayne County Employees' Retirement System, and Plaintiff Vladimir Zhukov
Professor Pollard	Professor Sir Andrew J. Pollard, Director of Oxford Vaccine Group
PSLRA	Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4 *et seq.*
Rule 9(b)	Federal Rule of Civil Procedure 9(b)
SD/SD	Standard dose/standard dose
SEC	US Securities and Exchange Commission
Section 10(b)	Section 10(b) of the Exchange Act
Section 20(a)	Section 20(a) of the Exchange Act
SII	Serum Institute of India
SVB Leerink	SVB Leerink LLC
Tracy Decl.	Declaration of Marques S. Tracy, executed September 27, 2021
WHO	World Health Organization

PRELIMINARY STATEMENT

This securities fraud case is based on AZ's efforts—in partnership with Oxford University—to develop, manufacture, and distribute a vaccine for COVID-19, a highly contagious disease caused by the SARS-CoV-2 virus that, since early 2020, has killed millions and infected hundreds of millions more. From the beginning, AZ warned that its efforts to develop the vaccine might fail; that the vaccine might not be efficacious or safe; and that regulatory authorizations or approvals might never come. AZ also made clear this was no ordinary commercial endeavor. Rather, AZ committed to providing fair and equitable access to the vaccine, particularly for low- and middle-income countries; to furnishing the vaccine at no profit during the pandemic; and to scaling up a massive manufacturing effort at its own risk. AZ was true to its word. As of today, the vaccine—referred to as AZD1222 in the AC—has been authorized or approved for use by multiple regulators around the world, and it is presently in use in over 170 countries. So far, over 1.1 billion doses of the vaccine have been released, with approximately two-thirds going to low- and middle-income countries, saving countless lives.

Plaintiffs do not dispute any of these facts, which are reflected in their AC or are a matter of public record. Instead, and against all logic, Plaintiffs would have this Court believe that a pharmaceutical company would invest billions of dollars to develop a vaccine it knew would not be approved based on clinical trials it knew were flawed. According to Plaintiffs, Defendants knew of certain "adverse facts" concerning late-stage clinical trials led by Oxford (in the UK, Brazil, and South Africa) that were not disclosed, rendering Defendants' statements about the vaccine false.

But many of those supposed "adverse facts" are based on Plaintiffs' selective (and misleading) quotations from AZ's public statements or were disclosed (not concealed), and in any event are nothing more than inactionable critiques of clinical trial design or execution. Indeed, as the AC admits and the public record shows, the clinical trial "miscues" to which Plaintiffs point were disclosed to regulators (who approved amended trial protocols in light of them), and—most critically—did not

alter the researchers' conclusions that the vaccine was efficacious and safe, with multiple regulators agreeing. The AC fails to state a claim and should be dismissed for at least the following three reasons.

First, Plaintiffs fail to plead an actionable misstatement or omission. The vast majority of statements Plaintiffs challenge—describing progress of the clinical trials, interpreting clinical trial results, and reiterating AZ's commitment to the highest standards—are inactionable opinions, statements of corporate optimism, or FLS shielded by the PLSRA. Nor was AZ under any duty to disclose the purportedly concealed "adverse facts." And the AC's ultimate assertion—that Defendants failed to disclose that AZD1222 "was unlikely to be approved for commercial use in the U.S. in the short term," *e.g.*, ¶ 48(h)—betrays the fundamental flaws in this case. Even putting aside that AZ committed to providing the vaccine at no profit during the pandemic, AZ never suggested, much less guaranteed, *any* approval for "commercial use," *any*where, at *any* time. Defendants were not required to paint the defeatist picture Plaintiffs insist.

Second, Plaintiffs fail to plead particularized facts to support a compelling inference that Defendants acted with scienter. The AC's attempt to plead motive is woefully flawed: (1) Plaintiffs do not (and cannot) plead any stock sale by any Individual Defendant, affirmatively undermining any inference of scienter; (2) that AZD1222 was an "important and high-profile drug candidate[]" suggests nothing more than a generalized motive to appear successful, a "motive" courts routinely reject; and (3) the AC nowhere pleads the requisite "unique connection" between Defendants' statements about AZD1222 and AZ's stock-based acquisition of Alexion (a company in the rare disease space), leaving only a generic motive to inflate stock price to engage in M&A activity, which is legally insufficient. The AC's attempt to plead recklessness also falls far short of the mark. The AC fails to identify a single piece of information (let alone contradictory information) to which the Individual Defendants had access when they made their challenged statements, pointing instead to generalized assertions about what each would or should have known. The pleaded and undisputed facts instead show only

nonfraudulent intent: in the middle of a pandemic during which it would not profit, AZ partnered with world-leading experts at Oxford—who made virtually identical public disclosures at almost every step—and others to develop, manufacture, and distribute a vaccine to bring this deadly pandemic to an end, and did it in record time and under unprecedented conditions.

Third, the AC fails to plead loss causation. The "corrective" disclosures to which Plaintiffs point—providing further details about clinical trial design, methodology, and execution; and press/analyst commentary questioning trial results or speculating about future approvals—are not "corrective" at all. They did not disclose anything new, much less reveal any supposed hidden fraud.

Because these pleading deficiencies (and others described below) cannot be cured, the AC should be dismissed with prejudice.

BACKGROUND[1]

A. AZ and AZD1222

AZ is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines, with three primary therapy areas during the CP: Oncology (accounting for 42% of approx. $26 billion in 2020 product sales), CVRM (accounting for 27%), and Respiratory & Immunology (accounting for 21%). Ex.57 at 1-2. Each area offers a number of different products, with dozens more in the pipeline. *Id.* at 30-51. AZ securities are traded on London, Stockholm, and US exchanges. Ex.24.

On March 27, 2020, Oxford announced that its researchers were working on a potential COVID-19 vaccine, later called AZD1222. Ex.2. AZD1222 is a recombinant adenovirus vaccine that uses a viral vector based on a weakened version of the common cold containing the genetic

[1] This section is taken from the AC's well-pleaded factual allegations, documents referenced therein, and documents that may be judicially noticed—including SEC filings, press releases, conference call transcripts, and press coverage—and thus may be considered on this motion. *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007); *Rudani v. Ideanomics, Inc.*, 2020 WL 5770356, *1 n.1 (S.D.N.Y. Sept. 25, 2020); *In re Express Scripts Holding Co. Sec. Litig.*, 2017 WL 3278930, *8-10 (S.D.N.Y. Aug. 1, 2017).

material of SARS-CoV-2 spike protein, which (after vaccination) primes the immune system to attack the virus. ¶ 33; Ex.4. According to the AC, it uses a "more tried and tested vaccine approach[]" than mRNA vaccines. ¶ 32; *see* Ex.35; Ex.44. Critically for global vaccination efforts, AZD1222 is inexpensive to manufacture, and easier to mass produce, store, transport, and handle than mRNA vaccines because it does not require sub-zero temperature storage and can be administered within existing healthcare settings. ¶ 32; Ex.34; Ex.35; Ex.44.

Before, during and after the CP, AZ repeatedly stressed its commitment to broad and equitable access to AZD1222, including in low- and middle-income countries, and that it was engaging with various international organizations and governments for the fair allocation and distribution of the vaccine. ¶¶ 38, 39, 47, 60, 61; *e.g.,* Ex.18; Ex.29 at 23; Ex.56; Ex.62 at 4. And throughout, AZ committed to supply AZD1222 at no profit during the pandemic. ¶¶ 36, 38; *e.g.*, Ex.6; Ex.8; Ex.9; Ex.18; Ex.29; Ex.56.

B. AZ's Partnership With Oxford, Initial Government Commitments, and the Oxford-Led Phase I/II UK Trial

By the end of March 2020, Oxford researchers were screening healthy volunteers, aged 18-55, for a vaccine trial in the UK with up to 510 participants. ¶ 30; Ex.2. On April 23, Oxford announced that it had begun testing, adding that around 1,110 people aged 18-55 would take part in the trial. Ex.3. Oxford detailed that participants would receive either the COVID-19 vaccine or a meningitis vaccine (as the former was expected to cause minor side effects not produced by a saline control), and either one or two doses. *Id.* Oxford warned that the vaccine might not work, noting that "a significant proportion of vaccines that are tested in clinical trials don't work." *Id.*

Thereafter, on April 30, AZ and Oxford announced an agreement for the development and global distribution of Oxford's COVID-19 vaccine, combining Oxford's world-class expertise in vaccinology and AZ's global development, manufacturing, and distribution capabilities. ¶¶ 30-31; Ex.4; Ex.5. The joint announcement reiterated that the "potential" vaccine had already entered Phase

I clinical trials involving healthy volunteers aged 18-55 years, across five sites in the UK. Ex.4. Oxford further noted that the partnership would allow for rapid vaccination around the world "if the COVID-19 vaccine candidate proves to be effective." Ex.5.

Governments and international organizations almost immediately began offering their support. On May 21, AZ announced that it had concluded the first agreements for at least 400 million doses of the vaccine and had secured total manufacturing capacity for one billion doses. ¶ 38; Ex.6. AZ also announced that it had received over $1 billion from the US BARDA, which called for a US development program including a Phase III clinical trial with 30,000 participants and a pediatric trial. ¶ 38; Ex.6. AZ noted the pending Oxford-led Phase I/II clinical trial in the UK (later referred to as "COV001"), adding that data "is expected shortly which, if positive, would lead to late-stage trials in a number of countries," and warning that "the vaccine may not work but [AZ] is committed to progressing the clinical program with speed and scaling up manufacturing at risk." ¶ 38; Ex.6.

C. Oxford Begins Phase II/III Trials in Several Countries and Commitments Continue

As the pandemic spread and countries were locking down, the Oxford-led trials continued. On May 22, Oxford detailed that its Phase II trial in the UK would enroll up to 10,260 participants, including "a small number of older adults" for groups aged 56-69 and 70+. Ex.7. Oxford added that its Phase III part of the study would assess how the vaccine works "in a large number of people over the age of 18," and noted that participants would receive either one or two doses. *Id.* Oxford again warned that "[a] significant proportion of vaccines that are tested in clinical trials don't work." *Id.*

On June 4 and 13, AZ announced a $750 million agreement with CEPI and Gavi for 300 million doses, an agreement with Europe's IVA to supply up to 400 million doses, and a licensing agreement with SII to supply one billion doses for low- and middle-income countries. ¶¶ 39, 44; Ex.8; Ex.9. Both announcements noted that, in addition to Oxford's ongoing Phase II/III UK trial (later referred to as "COV002"), "[o]ther late-stage trials are due to begin in a number of countries." Ex.8;

Ex.9. Both also again warned that "the vaccine may not work," but that AZ was committed to progressing the clinical program "with speed and scaling up manufacturing at risk." Ex.8; Ex.9. The AC starts the class period on June 15. ¶ 1.

On June 28, Oxford announced the start of a Phase III trial in Brazil (later referred to as "COV003"), with late-stage trials ongoing in the UK and South Africa (later referred to as "COV005"). Ex.10.

D. Oxford and AZ Publish Interim Results for Phase I/II UK Trial

On July 20, Oxford and AZ issued releases citing publication of interim results from COV001, with 1,077 healthy adult participants aged 18-55 having received one or two doses, by Oxford researchers in the medical journal *The Lancet*. ¶ 47; Ex.12; Ex.13. The interim results showed that the vaccine was tolerated and generated robust immune responses in all evaluated participants. ¶ 47; Ex.12. AZ noted that late-stage Phase II/III trials were underway in the UK, Brazil, and South Africa and were due to start in the US, and would determine safety and immune responses "in different age ranges and at various doses." ¶ 47; Ex.12. The *Lancet* publication of the same date provided 11 pages of granular detail about COV001 and its analysis. Ex.14.

On July 30, AZ filed its Form 6-K for the six months ended June 30, 2020, reporting on, *inter alia*, status of the trials. ¶ 49; Ex.15 at 33. AZ noted that initial data from COV001 had been reviewed by a DSMB and the MHRA, "resulting in the advancement to the COV002 Phase II/III trial in the UK, with over 10,000 participants." ¶ 49; Ex.15 at 33. AZ referenced the prior launches of COV0002, COV0003, and COV0005, noting that those trials would assess safety and immune responses "in different age ranges, at various doses." ¶¶ 49-50; Ex.15 at 2.

During an earnings conference call the same day, Dr. Pangalos was asked about the strength of the COV001 data as compared to vaccine competitors, and he responded:

> I think we're very pleased that both our data shows that we're getting a good level of neutralizing antibody presentation in the patients that are vaccinated with the 2 doses

as well as a good T cell response. The study remains on track.

¶ 52; Ex.16 at 17. He also explained that the data readouts from the UK, Brazil, or South Africa, or in combination, "could be sufficient for regulatory approvals around the world." ¶ 53; Ex.16 at 24. Mr. Soriot added that the program had moved quickly to trials outside the UK (where the attack rate was then-low) to Brazil and South Africa (where the infection rate was then-high), to better ensure statistically meaningful results. Ex.16 at 24; *see* Ex.39. In response to questions about timing of data for "elderly" participants, and the possibility of pulling data across studies, Dr. Pangalos responded:

> [D]ata on different age groups is coming from [COV001] and [COV002], and we're getting that data in on a weekly basis. And with regards to pulling data from U.K., Brazil and African studies, the answer is, yes, we can because the endpoints are exactly the same. So we would be able to pull the data for the filing.

¶ 54; Ex.16 at 41-42.[2]

On August 14, AZ announced an agreement with the EC to supply 400 million doses, and repeated that clinical development of AZD1222 was "progressing globally" with ongoing trials in the UK, Brazil, and South Africa, and trials planned in the US, Japan, and Russia. ¶ 57; Ex.18.

E. Phase III US Trial and AZ Reiterates Its Commitment to "Highest" Standards

On August 31, AZ announced it had expanded into a Phase III clinical trial in the US. ¶ 61; Ex.19. The release offered various details about the trial (referred to as "D8110C00001"), which would be led by AZ, *see* ¶ 138; Ex.21: participants would include healthy adults or those living with medically stable chronic disease; participants would receive two doses of either the vaccine or a saline control; and randomization of the treatment would be stratified across two age groups—18-65 and 65+—with at least 25% of participants aged 65+. Ex.19. The release also referenced and linked a separate announcement issued the same day, reiterating AZ's commitment to "follow the science," "put patients first," adhere to the "highest" scientific, clinical, and safety standards, and ensure that

[2] The Forms 6-K and conference call transcripts and materials—from both the July and November 2020 earnings calls—included FLS disclaimers and detailed various risk that could impact FLS. *See infra* at Point I.A.6 & Annex B.

AZ's market authorization submissions "meet the stringent requirements established by regulators" around the globe. ¶¶ 60-61; Ex.19; Ex.20.

On September 8, it was announced that Mr. Soriot and eight other pharmaceutical company CEOs had signed a pledge on behalf of their companies to "make the safety and well-being of vaccinated individuals our top priority," adhere to "high scientific and ethical standards" for clinical trials and manufacturing processes, and seek regulatory authorization or approval only after demonstrating safety and efficacy through a Phase III clinical study designed and conducted to meet expert regulatory requirements. ¶ 63; Ex.22.

AZ demonstrated its commitment the next day, when it announced that, per standard procedure, vaccination in all trials had been voluntarily paused to allow independent review of safety data from a single event of unexplained illness in COV002. Ex.23. Mr. Soriot stated that "[t]his temporary pause is living proof" that "we put science, safety and the interests of society at the heart of our work." *Id.*[3] On September 12, AZ announced that trials had resumed in the UK, Ex.25, and by late October, AZ announced that trials had resumed across the world with regulators confirming that it was safe to do so, Ex.26.

F. Oxford and AZ Release Results From the Oxford-Led Phase II/III Trials

On October 24, during IDWeek—the joint annual meeting of various infectious diseases, epidemiology and other health professional associations, Ex.68—Oxford's Professor Pollard previewed certain COV002 results, including on "immunogenicity and safety in older adults." Ex.27. Professor Pollard reiterated that the trial participants were healthy adults in groups aged 18-55, 56-69, and ≥70 years, and explained that "[i]mmune responses were demonstrated across all ages, with stronger antibody responses after a second dose of vaccine administered 1 month after the first." *Id.*

[3] According to the AC, Mr. Soriot addressed the pause at a JPMorgan Healthcare CEO conference call series the prior day, and "expressed his confidence in the design of the trials, safety protocols and DSM." ¶¶ 66-67.

In addition, "[l]ocal and systemic reactogenicity was lower at older ages than in younger adults and lower after the second dose then after the first." *Id.* Press reported on these results, including an October 26, 2020 CNBC article quoting an AZ spokesperson who repeated, "It is encouraging to see immunogenicity responses were similar between older and younger adults and that reactogenicity was lower in older adults, where the COVID-19 disease severity is higher." ¶ 70; Ex.28.

On November 5, AZ filed its Form 6-K for the nine months ended September 30, 2020, again reporting on, *inter alia*, progress in the trials. ¶ 72; Ex.29 at 23, 34. The 6-K repeated the EMA's October 2020 announcement that the CHMP had started a rolling review of data for AZD1222, the first in the EU for a COVID-19 vaccine. ¶ 72; Ex.29 at 34. The 6-K also referenced the data presented by Oxford at IDWeek, ¶ 72; Ex.29 at 34, and the vaccine pledge, ¶ 73; Ex.29 at 5, 23.

During an earnings call the same day, Dr. Pangalos observed that "[p]rogress has been made with our vaccine, AZD1222, and we have now resumed dosing in all our trials globally, alongside entering a rolling regulatory review in Europe." ¶ 75; Ex.30 at 13. In response to a question regarding the regulatory approval process, he answered that "there's nothing from the interactions that we've had with either the [EMA] or the MHRA that is giving us pause that if we demonstrate efficacy and safety in the data set that we have in the studies that are ongoing across Brazil, U.K. and Africa that we won't be able to get an approval." ¶ 75; Ex.30 at 37-38. When asked about whether there would be data on "elderly" patients, Dr. Pangalos referenced Professor Pollard's IDWeek presentation, which "showed that the immune response in the 56 to 69 year olds and . . . 70 and above looks very similar to the response of the 18 to 55 year olds. . . . [W]e're feeling good about the immunogenicity in all the age groups that we're testing. And we think we will have data from those age groups for the readout." ¶ 76; Ex.30 at 21.[4]

[4] Mr. Soriot separately observed that efforts against the COVID-19 pandemic "include advancing the vaccine candidate and more importantly initiating Phase 3 trials for our long-acting antibody combination, which is incredibly promising and

This optimism was confirmed later that month. On November 19, Oxford announced results regarding immunogenicity and safety from the Phase II component of COV002, showing that the vaccine was equally as effective at provoking an immune response across all ages 18+, and was better tolerated in adults aged 56+ than younger adults. Ex.32; Ex.33 at 1979-80. Those results were also disclosed in a paper by Oxford researchers published in *The Lancet*, which provided 14 pages of granular detail, including:

- both "low dose" and "standard dose" regimens had been used, after a June 5 protocol amendment;
- recruitment started with adults aged 18-55, for the low dose regimen, and expanded to 56-69 and then to 70+ only after safety review by a DSMB and a minimum of two weeks of safety and immunogenicity data before recruitment to each successive age cohort; and
- the 18-55 group received two doses, while the 56-59 and 70+ groups received one or two.

Ex.33 at 1979, 1982.[5]

According to Plaintiffs, the "[t]ruth [b]eg[an] to [e]merge" on November 23, AC at 34, when Oxford and AZ each issued releases describing positive high-level results regarding efficacy and safety from an interim analysis of pooled data from COV002 and COV003, which showed that the vaccine was highly effective in preventing COVID-19, with no hospitalizations or severe cases reported in participants receiving the vaccine, ¶ 78; Ex.34; Ex.35. The releases repeated that two different dosing regimens had been used, further detailing that one provided a half dose followed by a full dose (LD/SD), and the other provided two full doses (SD/SD)—and both met the primary efficacy endpoint per an independent DSMB, with 90% and 62% efficacy, respectively. Ex.34; Ex.35. AZ also disclosed that it would seek an EUL from the WHO for an accelerated pathway to vaccine

it's a potential new medicine called AZD7442." Ex.30 at 4. The AC omits the last few words, ¶ 74, which make clear that Mr. Soriot was characterizing the "promising" AZD7442, a different COVID-19 medication, Ex.30 at 4, 17.

[5] The *Lancet* article disclosed that the data reviewed for the immunogenicity analysis came from 560 participants: 160 aged 18-55, 160 aged 56-69, and 240 aged 70+. Ex.33 at 1979.

availability in low-income countries, and submit the full analysis of interim results for publication in a peer-reviewed journal. Ex.34; Ex.35.

The AC alleges that the November 23 announcements raised questions from analysts and others, ¶ 78, causing AZ to further detail the genesis behind the LD/SD and SD/SD dosing regimens: one of the third-party manufacturers of doses for the trial used a different measuring technique, resulting in a lower viral particle concentration for its doses; once this was discovered, researchers raised it with regulators and the trial protocol was amended on June 5 to include the LD/SD regimen (which used those doses) and an SD/SD regimen. ¶¶ 40-42, 81, 139; *see* Ex.42 at 101. The November 23 announcements also allegedly caused some to highlight that the LD/SD regimen was given to a smaller number of participants and only to persons 18-55 (as they had been recruited first). ¶ 82. None, however, disputed that *both* regimens exceeded 50% efficacy, which both the FDA and WHO had indicated was the recommended threshold for approval. Ex.11; Ex.42 at 109.

The AC further alleges that, after the November 23 announcements, analysts, and reporters "widely panned" the supposed faulty clinical trial design and execution of COV0002 and COV003, claiming the results were based on "cherry-picked . . . data" and "very shaky science." ¶ 83:

- An SVB Leerink analyst published a November 23 note in which he accused AZ of "embellish[ing]" efficacy results by (accurately) reporting both the 90% and 62% efficacy numbers. ¶ 86; Ex.37. But in his same-day interview—which the AC misleadingly excerpts, ¶ 87—the analyst made clear his concern was with placing too much reliance on the 90% efficacy figure. The analyst underscored "it's great news for everybody that we have multiple vaccines that are hitting the mark in terms of efficacy in pivotal trials." Ex.38.[6]

- A November 23 Guggenheim report noted that nothing "would have predicted" the 90% vs. 62% efficacy outcomes for the two dosing regimens, but also stated that "[u]ltimately, we are encouraged by the data and think the interim results will lead to an approvable product in the ex-U.S. and the U.S. to help address the pandemic." ¶ 88; Ex.36.

- *Wired* published a November 25 report by a health consumer advocate who leveled various

[6] Without access to the US trial data, this analyst also predicted that AZD1222 would not be licensed in the US, and predicted—wrongly—that the November 23 results "put[] into question" the outlook for J&J's COVID-19 vaccine. ¶ 86; Ex.37. He further questioned safety results, ¶ 86; Ex.37, but the AC nowhere claims safety-related omissions.

> critiques of the trial, including that it was based on separate studies with data pooled across them, that different dosing and control injections were used, and that the studies used relatively few adults older than 55—all previously disclosed. ¶ 83; Ex.39.

The AC alleges that the November 23 announcements, and the negative response, caused the price of AZ ADSs to fall 5% over a 3-day period until the November 25 market close. ¶ 92.[7]

As promised, on December 8, AZ announced that results of an interim analysis from COV001, COV002, COV003 and COV005 had been published by Oxford researchers in *The Lancet* that day—the first peer-reviewed publication of Phase III data of any COVID-19 vaccine. Ex.41; *see* Ex.43. The *Lancet* study confirmed the top line efficacy results from the November 23 announcements and reported that there were no serious safety events related to the vaccine. Ex.42.[8] AZ also announced that submission of the data to regulatory authorities around the world had already begun. Ex.41.

The 12-page *Lancet* publication reiterated detail regarding, *inter alia*, the June 5 protocol amendment and LD/SD and SD/SD regimens—including that the two regimens were disclosed to, and approved by, UK health regulators, ¶103; Ex.42 at 101—and described a July 20 protocol amendment that had been made due to then-rolling study results: 18-55 year old cohorts were originally intended as single dose cohorts, but a second dose was later offered based on "robust booster responses identified in the evaluation of the early immunogenicity cohorts." ¶¶ 102-103; Ex. 42 at 101. By the time additional vaccine dose batches were manufactured for certain participants in these cohorts, more than four weeks (per trial design) had elapsed between first and second dose. ¶¶ 102-104; Ex.42 at 101-02, 105. The authors explained that there was "no significant difference in

[7] The AC also cites a November 26 *Daily Mail* article that falsely asserts that England's CMO "refused to support" the vaccine. ¶ 95. Rather, he stated that judgment about the vaccine's efficiency and safety should be left with the MHRA, who would assess based on data and peer-reviewed papers. Ex.40.

[8] Efficacy data was pooled from COV002 and COV003, and safety data was pooled from all four studies. Ex.42 at 100. Regarding pooling, the Oxford authors described: "Despite minor differences across the studies, there is sufficient consistency to justify the proposal for pooled analysis of data, which will provide greater precision for both efficacy and safety outcomes than can be achieved in individual studies and provides a broader understanding of the use of the vaccine in different populations." Ex.42 at 101.

efficacy estimates when comparing those with a short time window between doses (<6 weeks) and those with longer (≥6 weeks) . . . ." Ex.42 at 108.[9]

On December 14, the *Daily Mail* reported on an upcoming BBC Panorama episode for which Dr. Pangalos and others were interviewed. Dr. Pangalos made the unremarkable observation—given the unprecedented circumstance of racing to develop a vaccine amidst a pandemic—that "[t]here is no doubt I think that we would have run the study a little bit differently if we had been doing it from scratch." ¶ 114; Ex.48. Dr. Pangalos went on to say—which the AC omits—that "ultimately it is what it is and I think the Oxford group have done a fantastic job and then we've done as good a job as we possibly can to translate that into the data-set that we can provide to the regulators and to regions around the world for the approval." Ex.48. According to the AC, the price of AZ ADSs declined by approximately 8% as a result of Dr. Pangalos' statements. ¶ 114.[10]

G. The Ex-US Phase II/III Results Lead to Approvals Around the World

Based on the reported data, regulators around the globe acted:

- On December 30, AZ announced that AZD1222 was approved for emergency supply in the UK for those 18+, without age cutoff. ¶ 115; Ex.51.
- On January 6, 2021, AZ announced EUA for adults in India, Argentina, the Dominican Republic, El Salvador, Mexico, and Morocco. Ex.52.
- On January 29—the last day of the CP—following review by the CHMP, AZ announced the grant of CMA in the EU for adults 18+, without age cutoff. ¶ 120; Ex.53; Ex.54 at 174.[11]
- On February 15, AZ announced the WHO's grant of EUL for individuals 18 years+, again without age cutoff. Ex.56.

[9] The AC likewise alleges negative reaction to the published data, ¶¶ 107-113, but the cited sources nowhere dispute that primary efficacy had been met and the absence of safety issues, and consistently underscored the value of AZD1222 for global vaccination, given cost and ease of transport, *see, e.g.*, Ex.43; Ex.45; Ex.46.

[10] Professor Pollard, also interviewed, relayed that "[t]he key point here being it is a highly efficacious vaccine that is going to have a huge impact on the pandemic if we can get it licensed and then rolled out." Ex.48.

[11] While the AC excerpts portions of the EMA Assessment Report noting the low number of COVID-19 cases for participants 55+, ¶¶ 120-21, the AC omits the very next sections, which expressly found that, taking into account the safety and immunogenicity profile across all age groups, and experience with other vaccines, "the benefit/risk balance can be considered positive" for age groups 56-65 and 65+, Ex.54 at 165, 171-72.

These authorizations and approvals were sought and obtained less than a year after the WHO declared a global pandemic, Ex.1, and when it normally takes 15-16 years to develop a vaccine, ¶ 23; *see* Ex.44 ("Developing vaccines is hard, and it is common for the work to fall behind schedule. . . . [AZ's] and Oxford's vaccine is likely to be among the fastest ever developed.").

H. The US Phase III Clinical Trials and Current Status

Meanwhile, the AZ-led US Phase III trial was ongoing. On March 22, AZ announced high-level results from an interim analysis for the trial, which showed that the vaccine was 79% effective at preventing symptomatic COVID-19 (80% for adults 65+), and 100% effective at preventing severe disease and hospitalization. ¶ 128; Ex.59. The next day, the DSMB expressed concern with AZ's release, as the 79% efficacy calculation was based on data through February 17, while the DSMB had expected data for an additional month to be used, as there were still some possible COVID-19 cases as of February 17 to be adjudicated. ¶¶ 129-130; *see* Ex.60. Although again omitted from the AC, on March 25, AZ announced that primary analysis using the additional data showed vaccine efficacy for preventing symptomatic COVID-19 at 76% (rather than 79%), but with such efficacy at 85% (not 80%) in adults 65+, and again 100% for preventing severe disease and hospitalization. Ex.61.

On July 29, 2021, AZ announced that, with three other vaccines having already received EUA in the US and sufficient supply here, it would forgo seeking EUA and instead intended to seek full regulatory approval, which requires a more extensive BLA submission. Ex.64; Ex.65; Ex.66. Only one vaccine has been granted full regulatory approval in the US, recently on August 23. Ex.66.

To date, AZD1222 is being used in over 170 countries (more than any other COVID-19 vaccine). Ex.67. Over 1.1 billion doses of the vaccine have been released across the world (again, more than any other COVID-19 vaccine), with approximately two-thirds going to low- and middle-income countries. Ex.62 at 4; Ex.63.

I. The AC

The AC challenges portions of 12 statements—through press releases, SEC filings, earnings calls, and elsewhere—made between June 13 and November 5, 2020, concerning supply agreements for vaccine doses; the Oxford-led ex-US clinical trials, their progress, and data from them; and AZ's commitment to the "highest" standards, to "follow the science," and to "put patients first." ¶¶ 44, 47, 49-54, 57, 60-61, 63, 67, 70, 72-76 (*see* Annex A).

According to the AC, these statements were false due to the supposed omission of the following alleged "adverse facts" pertaining to COV002, COV003, and COV005:

> (1) two alleged trial "miscues," ¶ 6, that (i) certain participants received a LD/SD regimen as a result of supposed "manufacturing error" by a third party, and (ii) certain participants received their second dose later than the original trial design;
>
> (2) the trials consisted of a "patchwork of disparate patient subgroups, each with subtly different treatments," supposedly undermining any conclusions that could be drawn from the trial data;
>
> (3) the trials failed to include a substantial number of patients over 55, and no patients over 55 in the LD/SD regimen;
>
> (4) the trials were "hamstrung by widespread flaws in design, errors in execution, and a failure to properly coordinate and communicate with regulatory authorities and the general public";
>
> (5) the trials failed to follow applicable protocols, were not conducted in accordance with best practices and acceptable standards, and their data was of limited utility; and
>
> (6) as a result, AZD1222 was "unlikely to be approved for commercial use in the U.S. in the short term."

¶¶ 48, 56, 58, 62, 64, 68, 71, 77; *see also* ¶¶ 3-6.[12]

ARGUMENT

POINT I: THE AC FAILS TO PLEAD A SECTION 10(B) CLAIM

To state a claim under Section 10(b), Plaintiffs must plead facts showing (1) a material

[12] None of these purportedly undisclosed "adverse facts" pertains to the US Phase III trials. Plaintiffs allege no "adverse facts" regarding, or criticisms of, the US trial's design or execution, although the AC criticizes the data rollout that took place after the CP, in March 2021. ¶¶ 128-131; *see supra* at 14.

misrepresentation or omission; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation. *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, 552 U.S. 148, 157 (2008). In addition to the requirements under *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544, 570 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), that Plaintiffs allege "facts" establishing a "plausible" claim, Plaintiffs must also satisfy the heightened pleading requirements of both Rule 9(b) and the PSLRA, *ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009).

The PSLRA requires that Plaintiffs (i) "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if [such] allegation . . . is made on information and belief, . . . state with particularity all facts on which that belief is formed"; and (ii) "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" (scienter). 15 U.S.C. § 78u-4(b)(1), (2)(A); *Maloney v. Ollie's Bargain Outlet Holdings, Inc.*, 518 F. Supp. 3d 772, 777 (S.D.N.Y. 2021). The AC fails to allege a Section 10(b) claim for multiple, independent reasons, including because it fails to adequately allege (i) an actionable misstatement or omission; (ii) scienter; or (iii) loss causation, consistent with these high pleading standards.

A. The AC Fails to Allege an Actionable Misrepresentation or Omission[13]

Plaintiffs "must do more" than allege statements were false or misleading; "they must demonstrate with specificity why and how that is so." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004). Further, it is well-settled that silence, absent a duty to disclose, is not actionable. *Stratte-McClure*

[13] As an initial matter, it is difficult to ascertain which statements the AC challenges, as it engages in a puzzle-pleading approach that block quotes extensively, *e.g.*, ¶¶ 47, 60, 72, and then repeats the same set of assorted purported omissions, ¶¶ 48, 56, 58, 62, 64, 68, 71, 77. Plaintiffs fail to identify which quoted portions were false and because of which alleged omission(s)— leaving it to Defendants and the Court to sift through and determine exactly which statements Plaintiffs challenge and why, in violation of the PSLRA. *See Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x 32, 37-38 (2d Cir. 2012); *accord In re Alcatel Sec. Litig.*, 382 F. Supp. 2d 513, 534 (S.D.N.Y. 2005); *see also* 15 U.S.C. § 78u-4(b)(1). This memorandum primarily focuses on the portions that the AC highlights through ***bolded italics***.

v. Morgan Stanley, 776 F.3d 94, 100-01 (2d Cir. 2015). In an omissions-based case, Plaintiffs must allege either that a particular disclosure was required by statute or regulation (which they do not), or was necessary to make other statements not misleading. *Id.*; *In re Philip Morris Int'l Inc. Sec. Litig.*, 2021 WL 4135059, *10 (S.D.N.Y. Sept. 10, 2021) ("So long as the omission of information does not render disclosed statements misleading, . . . there is no generalized duty to disclose negative facts.").

The AC fails to meet these requirements. None of the challenged statements is rendered false by the purported non-disclosure of certain alleged "adverse facts," *see, e.g.*, ¶ 48(a)-(h), about the ex-US Phase II/III trials. In many instances, the allegedly withheld information was disclosed. Several of the statements are also inactionable puffery or opinions, or FLS protected by the PSLRA. At bottom—and ignoring the many authorizations and approvals already granted for AZD1222 and its extensive use around the world—the AC criticizes the design of COV002, COV003, and COV005, and complains that every single detail about the execution of those trials was not disclosed in real time. But there is no such disclosure duty, and supposedly flawed clinical trial design/execution is not actionable here as securities fraud. Nor are Defendants liable merely because they did not disclose all facts about the trials supposedly "cutting the other way," *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 189 (2015), as reasonable investors do not "expect that every fact known to an issuer supports" its opinions, *id.* at 190; *Tongue v. Sanofi*, 816 F.3d 199, 210 (2d Cir. 2016).

1. <u>The AC Pleads No False Statement Regarding Clinical Trial Status and Testing</u>

The AC challenges statements, reflected in AZ's June 13 and July 20, 2020 press releases and the July 2020 6-K, and during the July 2020 earnings call, that ex-US late-phase trials had started or were underway. ¶¶ 44, 47, 49-54. The AC nowhere disputes that the trials had begun; the statements were unquestionably true and thus are inactionable. *See In re EDAP TMS S.A. Sec. Litig.*, 2015 WL 5326166, *10 (S.D.N.Y. Sept. 14, 2015) (statements that "merely recite historical fact" inactionable); *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014) ("Neither immaterial false statements

nor material true statements are actionable."), *aff'd*, 604 F. App'x 62 (2d Cir. 2015); *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004).

The July 2020 press release and 6-K added that those trials would measure for immune responses "in different age ranges," ¶¶ 47, 50, and the AC complains that AZ falsely omitted that it "failed to include a substantial number of patients over 55 years of age," and none in the LD/SD regimen, ¶¶ 48(d), 56(d). Plaintiffs level a similar accusation because Dr. Pangalos, during the July 2020 conference call, responded to a question about timing for data on "elderly" participants by saying that data "on different age groups" was coming in on a weekly basis. ¶¶ 54, 56(d). But neither AZ nor Dr. Pangalos ever promised, identified, or even suggested *any* particular or minimum number of older adults in the ex-US Phase II/III studies. Rather, AZ and Oxford disclosed that COV001 included only participants aged 18-55, Phase II of COV002 would include a "small number of older adults" over 55, and Phase III of COV002 would include "a large number of people over the age of 18." Ex.2; Ex.3; Ex.4; Ex.6; Ex.7.[14] Regardless, Plaintiffs' cavil that the studies failed to include an undefined "substantial" number of patients aged 55+ is nothing more than an inactionable critique of trial design—which, of course, was proven wrong by the many authorizations and approvals the vaccine received. *See Kleinman v. Elan Corp., plc*, 706 F.3d 145, 153–55 (2d Cir. 2013) (plaintiff's criticisms of clinical study's methodology cannot, by themselves, raise actionable securities claim).[15]

The AC also fails in challenging an assortment of statements, made in the July 2020 6-K and August 14, 2020 press release, and during the July and November 2020 earnings calls, reporting progress in the ongoing ex-US trials: "During the period, [AZ] advanced its ongoing response to

[14] Not surprisingly, analysts picked this up. *See* ¶¶ 53 ("Is there something about the trial design, the single dose, or lack of elderly patients that might constrain you here?"), 76.

[15] *See also Abely v. Aeterna Zentaris Inc.*, 2013 WL 2399869, *7 (S.D.N.Y. May 29, 2013) ("The Second Circuit has emphasized that in scrutinizing a section 10(b) claim, a court does not judge the methodology of a drug trial, but whether a defendant's statements about that study were false and misleading."); *accord Davison v. Ventrus Biosciences, Inc.*, 2014 WL 1805242, *7 (S.D.N.Y. May 5, 2014); *In re Keryx Biopharmaceuticals, Inc. Sec. Litig.*, 2014 WL 585658, *10 (S.D.N.Y. Feb. 14, 2014).

address COVID-19," "[t]he study remains on track," clinical development is "progressing globally," and "[p]rogress has been made with our vaccine." ¶¶ 50, 52, 57, 75. These statements were unquestionably true, with trials launching, recruiting, and dosing patients, and obtaining results—which demonstrated efficacy and safety—on a rolling basis. *See supra* at 4-13. And the many authorizations and approvals ultimately secured, including during the CP, based on those results preclude any allegation that these progress statements were false.[16]

2. The AC Pleads No False Statement Regarding Clinical Trial Results

The AC next challenges statements "positive[ly]" describing initial or interim COV001 data and results, including the July 20, 2020 press release and July 2020 6-K and earnings call statements that those results showed AZD1222 was "tolerated and generated robust immune responses," and that the data had been independently reviewed, "resulting in the advancement" to COV002. ¶¶ 47, 49, 50, 51, 52. Similarly, the AC challenges Dr. Pangalos' statement, during the July 2020 earnings call, that "we're very pleased" the interim data shows "we're getting a good level of" antibody presentation and a "good T cell response." ¶ 52.

But Defendants' subjective interpretation of clinical trial data are opinions. *See Sanofi*, 816 F.3d at 214. Plaintiffs cannot manufacture falsity merely by quibbling with those opinions: to state a claim, Plaintiffs must allege that Defendants' interpretation was irrational or unreasonable, which they have not done and cannot do. *See id.* ("Plaintiffs [do not] allege that Defendants' interpretation of the data was irrational or unreasonable, and such an allegation would have little merit anyway, as the FDA eventually accepted [the product]."); *Kleinman*, 706 F.3d at 154 ("[W]here a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement.").[17]

[16] These statements are also inactionable puffery and opinion. *See infra* at Points I.A.2 & I.A.5.

[17] *See also Philip Morris*, 2021 WL 4135059, *12 ("Determining whether statements are plausibly alleged to be false . . . does not require the Court to choose between two competing analyses of data."); *EDAP*, 2015 WL 5326166, *10; *Davison*, 2014 WL 1805242, *8; *In re MELA Scis. Sec. Litig.*, 2012 WL 4466604, *13 (S.D.N.Y. Sept. 19, 2012).

Separately, Plaintiffs fail to plead liability for these opinions under *Omnicare*. They do not allege that any Defendant disbelieved his own stated opinion, or included a false embedded fact within it. 575 U.S. at 184-89. Nor, as demonstrated *infra* at Point I.A.4, have Plaintiffs offered particularized allegations showing that any of the supposedly omitted "adverse facts" would "conflict with what a reasonable investor would take from" the limited positive descriptions provided, *Sanofi*, 816 F.3d at 210, which is "no small task," *Omnicare*, 575 U.S. at 194.

Plaintiffs fare no better challenging statements, in an October 26, 2020 email to CNBC, in the November 2020 6-K, and during the November 2020 earnings call, repeating Professor Pollard's October 24 IDWeek presentation on COV002 results regarding immunogenicity: that immune responses were seen across each of the 18-55, 56-69, and 70+ age groups, and that reactogenicity was lower at older ages. ¶¶ 70, 72, 76. Even putting aside that these merely noted what Oxford previously presented, Plaintiffs do not, and cannot, claim that Defendants' interpretation of the data was irrational. Instead, the AC again appears to complain about the supposed omission that COV002 failed to include a "substantial" number of 55+ patients. ¶¶ 71(d), 77(d). But again, these statements did not guarantee, identify, or even suggest some minimum number of older participants in COV002.[18]

Finally, with respect to statements about whether the clinical trial results would lead to regulatory approvals, the AC nowhere identifies a single statement guaranteeing, or even predicting, that result. Rather, the AC challenges Dr. Pangalos' July 2020 earnings call observation that data readouts from across COV002, COV003, or COV005 "could be sufficient for regulatory review," ¶ 53, and his November 2020 earnings call statement that nothing in interactions with the EMA or MHRA "is giving us pause that if we demonstrate efficacy and safety" through the various ongoing trials, "that we won't be able to get an approval," ¶ 75. Nothing here was false. Both statements—

[18] Moreover, the immunogenicity data set came primarily from older adults. *See* n.5, *supra*.

like many others AZ and Oxford made—were expressly conditional and warned that authorizations or approvals might not ultimately be granted. *See* Annex B.

3. The AC Pleads No False Statement About Commitment to Science and Safety

The AC further challenges statements in two August 31, 2020 press releases, the September 8, 2020 pledge signed by Mr. Soriot, and the November 2020 6-K describing that pledge, stating that AZ was committed, and would adhere, to the highest safety, science, and clinical standards; its authorization submissions would meet regulatory submission requirements; and it would "follow the science" and "put patients first." ¶¶ 60, 61, 63, 73.

Such pledges and expressed commitments nowhere guaranteed the quality of AZD1222 (or the clinical trials), much less regulatory approval. As such, they were "too general to cause a reasonable investor to rely upon them," and are inactionable under the securities laws. *See ECA*, 553 F.3d at 206; *see also In re AT&T/DirecTV Now Sec. Litig.*, 480 F. Supp. 3d 507, 523-34 (S.D.N.Y. 2020) (company's commitment to "the highest standards" inactionable).[19] Regardless, the AC itself pleads AZ's commitment, recognizing, *inter alia,* prompt notification to regulators for protocol amendments, ¶¶ 42, 81, 139; *see also* Ex.33 at 1982; Ex.42 at 101; pausing studies pending independent review of potential safety issues, ¶¶ 65-67; *see also* Ex.23; and multiple regulatory authorizations and approvals obtained, ¶¶ 115, 120; *see also* Ex.51; Ex.52; Ex.53; Ex.54; Ex.56; Ex.58.

The AC additionally insists that the pledge Mr. Soriot signed on behalf of AZ was materially false because it promised to seek regulatory review only after demonstrating safety and efficacy through "a single" Phase III clinical study, when Oxford and AZ were conducting several Phase III studies across different sites. ¶¶ 63-64. That is nonsensical. No reasonable investor would think this

[19] *See also In re Philip Morris Int'l Inc. Sec. Litig.*, 437 F. Supp. 3d 329, 350-51 (S.D.N.Y. 2020) (company was "conducting extensive and rigorous scientific studies" and conducting "research [that] meets rigorous standards"); *In re MGT Cap. Invs., Inc. Sec. Litig.*, 2018 WL 1224945, *13 (S.D.N.Y. Feb. 27, 2018) (commitment to "the highest standards of transparency and corporate governance"); *Barrett v. PJT Partners Inc.*, 2017 WL 3995606, *6 (S.D.N.Y. Sept. 8, 2017) (commitment to adhering to "the highest ethical standards").

pledge was made to the exclusion of submitting data based on a number of studies, especially when Oxford and AZ repeatedly disclosed that they were conducting late-stage studies in various locations. ¶¶ 47, 49, 51-54, 57; *e.g.*, Ex.10; Ex.18; Ex.29 at 34.[20]

4. None of the Allegedly Non-Disclosed "Adverse Facts" Rendered Any Statement False

Plaintiffs' claims separately fail because the supposedly non-disclosed "adverse facts" about COV002, COV003, and COV005, *see, e.g.*, ¶ 48, cannot plead the falsity of any statement:

Alleged "manufacturing error" in COV002. What Plaintiffs label as "manufacturing error" in COV002, *e.g.*, ¶ 48(a), was instead a difference in measurement technique for viral particle concentration used by one third-party manufacturer, causing certain participants to get a lower dosage first shot, ¶¶ 40-41, 103; *see* Ex.42 at 101. Even putting aside that regulators were immediately notified of the issue, ¶¶ 42, 81, 139, Defendants never promised that a single dosing regimen would be used in COV002. To the contrary, AZ disclosed that the vaccine would be tested "at various doses." ¶¶ 47, 50; Ex.12; Ex.15 at 2.[21] Further, the AC nowhere disputes that efficacy was demonstrated using *both* the LD/SD and SD/SD regimens, or that it is the SD/SD regimen—*not* the LD/SD regimen that supposedly resulted from a "manufacturing error"—that is used around the world. Thus, that one manufacturer used a different measurement technique (leading to a LD/SD dosing regimen for certain trial participants) does not even "cut[] the other way." *Omnicare*, 575 U.S. at 189. More fundamentally, there is no duty to disclose such granular information about supposed clinical trial "miscues" as execution continues; to the contrary, the market expects some adjustments along the way, particularly with vaccine development in the middle of a worldwide pandemic. *See, e.g.*, *Kleinman*,

[20] Plaintiffs, of course, nowhere allege that seeking authorization or approval based on studies in multiple locations, or with pooled data, violates any particular rule or standard. Nor could they, given the numerous authorizations and approvals that followed. *See also* n.8, *supra*.

[21] And even before the "truth" supposedly "[b]eg[an] to emerge" on November 23, the November 19 *Lancet* publication noted that low and standard dose regimens were used, and approval of the June 5 protocol amendment. Ex.33 at 1982.

706 F.3d at 154-55 (no duty to disclose full methodology for calculating results where it was reasonable, even where methodology deviated from original study design and was not most rigorous available); *Keryx*, 2014 WL 585658, *10-12 (no "deep dive" disclosure required; "That plaintiffs would have preferred to have had more information regarding how the Phase 2 trial was performed and how the results were analyzed is irrelevant to a determination of actionable falsity.").[22]

Delay of certain second shots in COV002 and COV003. Plaintiffs' insistence that certain patients received a second shot outside the trial design's four-week window, *e.g.*, ¶ 48(c), fares no better, as this too was the result of normal iterative clinical trial work. Once early results showed "robust booster responses," those participants slated for a single dose (as was disclosed, Ex.7; Ex.12; Ex.13) were offered a second shot, and in some cases that could not be administered within the four-week window, ¶¶ 102-104; Ex.42 at 101-02, 105. Regardless, Plaintiffs do not and cannot allege that the delayed second shots had any ultimate impact on efficacy or the trial results. Ex.42 at 108. As such, there was no duty to disclose this trial execution detail, and it rendered no statement false.

Patchwork of patient groups and treatments. That the ex-US Phase II/III trials involved different patient groups with "subtly" different treatments, *e.g.*, ¶ 48(b), was disclosed throughout the CP: studies were ongoing in the UK, Brazil, and South Africa (and elsewhere), ¶¶ 47, 49, 50-54, 57, 72, 75; Ex.12; Ex.15 at 2; age groups were broken up differently, ¶¶ 47, 50, 54, 72, 76; Ex.7; Ex.15 at 2; Ex.19; Ex.27; different controls were used, Ex.19; Ex.21; and efficacy would be tested "at various

[22] *Accord Philip Morris*, 2021 WL 4135059, *9-10 (omission of fact that certain studies found cigarette-alternative product contained significantly larger amounts of some harmful chemicals than cigarettes did not render false defendants' positive statements about benefits of alternative product); *Lehmann v. Ohr Pharmaceutical Inc.*, 2019 WL 4572765, *3-4 (S.D.N.Y. Sept. 20, 2019) (omission of fact that trial failed to perform consistently with prior comparable studies did not render false defendants' description of results), *aff'd*, 830 F. App'x 349 (2d Cir. 2020); *In re Neurotrope Inc. Sec. Litig.*, 315 F. Supp. 3d 721, 728, 732 (S.D.N.Y. 2018) (omission of specific statistical methodology used for study did not make statements misleading even though methodology used was not "alleged industry norm"); *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 597-98 (S.D.N.Y. 2016) (non-disclosure that study did not meet primary efficacy endpoint did not render false statements that study showed certain respiratory advantages); *MELA*, 2012 WL 4466604, *13-14 ("[W]here the FDA eventually approved [the product] at least in part based on the results of the clinical trial . . . and defendants never guaranteed FDA approval, defendants had no obligation to disclose the purported flaws in the trial").

doses," ¶¶ 47, 50. Regardless, Plaintiffs' assertion that the "patchwork" nature "undermin[ed] the value" of the data is again nothing more than inactionable (and ultimately inaccurate) critique of the COV002 and COV003 trial design.

Patients 55+. AZ never suggested, identified or guaranteed any number of 55+ patients in COV002 or COV003—and instead Oxford's and AZ's disclosures made clear the numbers would be limited, Ex.2; Ex.3; Ex.4; Ex.6; Ex.7—and thus Plaintiffs' grouse that the studies failed to include a "substantial" number of patients 55+, and none in the LD/SD regimen, *e.g.*, ¶ 48(d), is again inactionable (and inaccurate) trial design critique.

Hamstrung by flaws, and failure to follow protocols and best practices. Plaintiffs conclusorily assert that COV002, COV003, and COV005 were "hamstrung" by various flaws and failed to follow various protocols, guidelines, and standards, again supposedly limiting the utility of the trial results, *e.g.*, ¶ 48(e)-(g), but identify no additional flaws, and no requirements or standards supposedly violated. Even putting aside that the trials were led by Oxford, and also ignoring the numerous authorizations and approvals obtained based on the trial data, Plaintiffs' conclusory criticisms are again not actionable as securities fraud. Defendants were not required to describe those trials, or AZD1222's prospects, in the negative way Plaintiffs propose. In fact, that would have been misleading given the many authorizations and approvals ultimately received based on those supposedly "flawed" trials. *See Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000) (corporate officials "need not present an overly gloomy picture of current performance and future prospects"); *Dalberth v. Xerox Corp.*, 766 F.3d 172, 186-87 (2d Cir. 2014) (company not required to "phrase disclosures in pejorative terms" or "frame its public information" as plaintiff would).

US approval in the short term. Weakest is Plaintiffs' ultimate assertion that Defendants failed to disclose that AZD1222 was "unlikely to be approved for commercial use in the U.S. in the short term." *E.g.*, ¶ 48(h). Defendants never promised *any* authorization or approval *anywhere* on *any*

timeline, but consistently warned that approvals might never come and that it was scaling up manufacturing at its own risk. Annex B. And while Plaintiffs selectively focus on the US market, AZ—even before the CP—consistently underscored its commitment to the fair and equitable distribution of AZD1222 around the world, and in particular to low- and middle-income countries. *E.g.*, ¶¶ 38, 39, 60; Ex.18; Ex.29 at 23; Ex.56; Ex.62 at 4.

5. The Remaining Challenged Statements Are Inactionable

Throughout, the AC challenges an assortment of statements of corporate optimism. ¶¶ 51 ("proud to be at the forefront and highly active in the pursuit of tackling" COVID-19), 52 ("study remains on track"), 67 (Soriot "expressed his confidence" in trial design, safety protocols and DSM), 75 ("[w]e continue to lead across multiple fronts" and "[p]rogress has been made" with vaccine).[23] Again, such statements are routinely recognized as inactionable puffery, as they are too generalized to be relied upon. *See ECA*, 553 F.3d at 206; *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 757-58 (S.D.N.Y. 2018) (company "made remarkable progress" toward commercialization of pipeline products; "confident about" what lays ahead; "proud" to be "on track" to have products reach market in 2016; "confident in these products").[24]

These statements are also opinions, *see In re Adient plc Sec. Litig.*, 2020 WL 1644018, *19 n.14 (S.D.N.Y. Apr. 2, 2020) ("progress" on goals and being "on track" are opinions), for which Plaintiffs again fail to allege liability under *Omnicare*. The AC nowhere alleges that the speakers (Dr. Pangalos and Mr. Soriot) did not believe their stated opinions, nor do the purportedly undisclosed "adverse

[23] The AC similarly challenges Mr. Soriot's "incredibly promising" statement, ¶ 74, but he was addressing AZD7442, an antibody combination for COVID-19, Ex.30 at 4, 17. Plaintiffs cannot plead a misstatement by mischaracterizing the statements on which they rely. *See Ft. Worth Emp'rs Ret. Fund v. Biovail*, 615 F. Supp. 2d 218, 221 (S.D.N.Y. 2009). Regardless, such characterization is unquestionably puffery. *See IBEW Local Union No. 58 Pension Trust Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC*, 783 F.3d 383, 392 (2d Cir. 2015) ("a promising start").

[24] *Accord Nguyen v. New Link Genetics Corp.*, 297 F. Supp. 3d 472, 489 (S.D.N.Y. 2018) ("confident" in study design and "encouraged" by progress); *see also In re Diebold Nixdorf, Inc., Sec. Litig.*, 2021 WL 1226627, *10 & n.13 (S.D.N.Y. Mar. 30, 2021) (expressing "confidence" in ability to integrate after merger) (citing cases).

facts" identified in the AC "substantially undermine the conclusion a reasonable investor would reach from" the opinions. *Philip Morris*, 2021 WL 4135059, *9. Indeed, the AC could not so plead, given the manufacturing commitments and efforts achieved, positive trial results obtained, authorizations and approvals granted, and doses released. *See also supra* Point I.A.4.[25]

6. Many of Defendants' Statements Are Protected Forward-Looking Statements

Under the PSLRA's safe harbor, there can be no liability for FLS where (1) the statements were accompanied by meaningful cautionary language; (2) the statements were immaterial; or (3) the plaintiff failed to prove the statements were made with actual knowledge that they were false or misleading. *Slayton v. Am. Express Co.*, 604 F.3d 758, 766 (2d Cir. 2010).

Many of the challenged statements—including concerning the clinical trial activity planned; the clinical trial data, what it would ultimately show, and how it would be used for regulatory submissions; standards to be followed for future regulatory submissions; and potential for regulatory approvals, *see* ¶¶ 47, 49, 50, 53, 54, 57, 60, 70, 72, 74, 75—are "classically forward-looking." *See Gillis*, 197 F. Supp. 3d at 585, 591; *see also Schaeffer v. Nabriva Therapeutics plc*, 2020 WL 7701463, *10 (S.D.N.Y. Apr. 28, 2020) (statements that defendants expected drug to win FDA approval and launch shortly after approval "are both forward-looking").[26]

Here, the first safe harbor applies, as AZ (and Oxford) routinely cautioned investors about the uncertainty of the ongoing clinical trials and the risks of non-approval. *See* Annex B. Courts have found similar warnings to be sufficiently cautionary for the safe harbor. *See, e.g.*, *Gregory*, 297 F. Supp. 3d at 404-05; *EDAP*, 2015 WL 5326166, *10.

---

[25] To the extent the AC challenges announcements of agreements to supply vaccine doses, *see* ¶¶ 44, 57, the AC again fails, as those agreements were unquestionably reached. See *supra* at 17-18.

[26] *See also Aratana*, 315 F. Supp. 3d at 758 (statements about defendants' "expectations regarding FDA approval and the timeline for . . . commercial release were framed as opinions, forward-looking statements, or both"); *Gregory v. ProNAi Therapeutics, Inc.*, 297 F. Supp. 3d 372, 403-04 (S.D.N.Y. 2018) (statements about scientific viability of drug are FLS), *aff'd*, 757 F. App'x 35 (2d Cir. 2018); *Biovail*, 615 F. Supp. 2d at 231-32 (statements about anticipated FDA approval are FLS).

Additionally, both the July and November 2020 earnings calls (and accompanying presentation materials), and the July and November 6-Ks, included FLS disclaimers, explaining that certain statements were protected FLS. Ex.15 at 21, 54-55; Ex.16 at 3; Ex.17; Ex.29 at 53-54; Ex.30 at 2-3; Ex.31. The documents also listed the "[i]mportant factors" or "principal risks and uncertainties" that could cause actual results to differ—including, *inter alia*, the failure to meet regulatory or ethical requirements. Ex.15 at 21, 54-55; Ex.17; Ex.29 at 53-54; Ex.31; Annex B. Again, such risk warnings are sufficient. *See EDAP*, 2015 WL 5326166, *7, 10; *Biovail*, 615 F. Supp. 2d at 232-33.

The third safe harbor separately shields the challenged statements because the AC does not even attempt to plead facts showing "actual knowledge" of falsity. *See infra* Point I.B.2. That is not remotely surprising, as the disclosed risks of non-approval never actually materialized.

B. The AC Fails to Plead the Requisite Strong Inference of Scienter

The AC also fails for the independent reason that it does not come close to pleading a "strong inference" of scienter—an "intent to deceive, manipulate, or defraud"—for any Defendant. 15 U.S.C. § 78u-4(b)(2); *Kalnit v. Eichler*, 264 F.3d 131, 138 (2d Cir. 2001). To qualify as "strong," the "inference of scienter must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007). A strong inference of scienter may be supported by alleging particularized facts showing (i) "motive and opportunity," or (ii) "strong circumstantial evidence of conscious misbehavior or recklessness." *ECA*, 553 F.3d at 198; *Tung v. Bristol-Myers Squibb Co.*, 412 F. Supp. 3d 453, 458-59 (S.D.N.Y. 2019). The AC does neither.

1. The AC Fails to Plead Motive

To plead motive, Plaintiffs must allege that the Individual Defendants benefitted in some "concrete and personal" way from the purported fraud. *Kalnit*, 264 F.3d at 139; *City of N. Miami Beach Police Officers' & Firefighters' Ret. Plan v. Nat'l Gen. Holdings Corp.*, 2021 WL 212337, *6 (S.D.N.Y. Jan.

21, 2021). The AC is devoid of any such allegations.

For example, it is well-settled that the absence of stock sales, as well as increased holdings over the CP, "substantially undermine[]" any inference of scienter. *See Tung*, 412 F. Supp. 3d at 459.[27] Plaintiffs nowhere allege that the Individual Defendants engaged in suspicious, unusual, or even *any* insider sales of AZ securities, on any exchange, during the CP. Nor could they. Indeed, AZ's SEC disclosure regarding CEO and CFO compensation shows that Messrs. Soriot and Dunoyer's AZ holdings *increased* over 2020. Ex.57 at 149.

Already behind the eight ball, Plaintiffs proffer two other supposed motives, neither of which is adequate. *First*, the AC alleges that AZD1222 was an "important and high-profile drug candidate[]" and that "[g]overnments, media, and the general public around the world were closely watching Defendants' progress in the development of AZD1222." ¶ 137. But this suggests nothing more than a motive to appear profitable or successful—a generalized motive common to most corporate officers, routinely found insufficient. *See Neurotrope*, 315 F. Supp. 3d at 735 (fact that drug product candidate was sole product, and success of company hinged on it, insufficient).[28] And given the microscope alleged, any motive to commit fraud *in full world view* strains credulity.

Second, the AC fares no better in alleging motive to artificially inflate AZ's stock price in order to fund its partly stock-based acquisition of Alexion, a leader in medications for rare immune diseases. ¶ 140; Ex.47. Such a desire constitutes adequate motive only in "narrow[]" circumstances, and only where plaintiffs plead a "unique connection" between the alleged fraud and the acquisition, and that

---

[27] *Accord In re Rockwell Med., Inc. Sec. Litig.*, 2018 WL 1725553,*12 (S.D.N.Y. Mar. 30, 2018); *Turner v. MagicJack VocalTec, Ltd.*, 2014 WL 406917, *11 (S.D.N.Y. Feb. 3, 2014); *Bristol-Myers*, 312 F. Supp. 2d at 561.

[28] *Accord Fialkov v. Alcobra Ltd.*, 2016 WL 1276455, *7 (S.D.N.Y. Mar. 30, 2016) ("The desire to have a drug application approved . . . can be ascribed to any pharmaceutical company."); *Koncelik v. Savient Pharm. Inc.*, 2010 WL 3910307, *6 (S.D.N.Y. Sept. 29, 2010) (motive to "maintain the perception of [a] drug's approvability" insufficient), *aff'd*, 448 F. App'x 154 (2d Cir. 2012); *In re Pfizer Inc. Sec. Litig.*, 538 F. Supp. 2d 621, 635 (S.D.N.Y. 2008) ("desperate need . . . to assure the financial community of the existence of a new blockbuster drug" insufficient); *Bristol-Myers*, 312 F. Supp. 2d at 560-61 (trying to "maintain a façade of future potential" for company's drug pipeline insufficient); *see also Nat'l Gen.*, 2021 WL 212337, *6 (motives common to most corporate officers, such as desire for corporation to appear profitable or successful are insufficient); *Maloney*, 518 F. Supp. 3d at 779 (desire to maintain "winning streak" insufficient).

the "misstatements directly relat[e] to the acquisition." *ECA*, 553 F.3d at 201 & n.6; *In re Agnico-Eagle Mines Ltd. Sec. Litig.*, 2013 WL 144041, *12 (S.D.N.Y. Jan. 14, 2013) (plaintiffs must plead that allegedly fraudulent inflation "was aimed at the specific acquisitions identified in the pleadings"), *aff'd*, 533 F. App'x 38 (2d Cir. 2013).

The AC nowhere alleges *any* connection, let alone a "unique connection," between (i) Defendants' statements regarding AZD1222 and efforts to stop a global pandemic, and (ii) the unrelated acquisition of Alexion, which makes rare immune disease medications. *See ECA*, 553 F.3d at 201 (motive not pleaded where "the link between the acquisition and the alleged misconduct simply is not close enough to strengthen the inference of an intent to defraud"); *Agnico-Eagle Mines*, 2013 WL 144041, *12, *16 (motive for corporation to facilitate otherwise routine mergers and acquisitions may demonstrate "laudable desire" to protect shareholder investments rather than intent to defraud).

Of course, Plaintiffs' failure to plead adequate motive here is hardly surprising, as AZ committed to support access to AZD1222 *at no profit* during the pandemic—a time period *without* horizon during the entire CP—and *at its own risk* should approvals not ultimately be granted.

2. The AC Fails to Plead Conscious Misbehavior or Recklessness

Without motive, circumstantial allegations of conscious misbehavior or recklessness "must be correspondingly greater." *Kalnit*, 264 F.3d at 142. Plaintiffs must plead behavior that is "highly unreasonable" and "an extreme departure from the standards of ordinary care," *id.*—in other words, "a state of mind approximating actual intent," *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009); *Tung*, 412 F. Supp. 3d at 460. The AC again falls far short.

Plaintiffs make the conclusory allegation that the Individual Defendants "recei[ved] information reflecting the true facts," ¶ 136, but nowhere "specifically identify the reports or statements" containing such alleged information, as they must. *Novak*, 216 F.3d at 309; *see also Nat'l Gen.*, 2021 WL 212337, *8-9. Indeed, Plaintiffs fail to cite a single internal document or CW showing

that defendants had any information contradicting their public statements about AZD1222. *See Fialkov*, 2016 WL 1276455, *7 (no scienter where "[p]laintiffs have not adequately alleged that either [individual defendant] had knowledge or access to information contradicting their statements about the Phase III study"); *accord Philip Morris*, 2021 WL 4135059, *14.[29]

Instead, Plaintiffs point to the June 5 protocol amendment for COV002 regarding LD/SD and SD/SD. ¶ 139. But Plaintiffs nowhere allege that any Individual Defendant had contemporaneous knowledge of this; indeed, the ex-US trials were led by Oxford. *See Abely*, 2013 WL 2399869, *19-20 (no scienter where third party was responsible for clinical trial design and execution). Regardless, even assuming Plaintiffs pleaded facts showing such awareness by the Individual Defendants, nothing about the protocol amendment rendered any challenged statement false, much less knowingly or recklessly so. *Supra* at 22-23.[30] Moreover, AZ and Oxford informed regulators about the dosing measurement discrepancy and amended the study protocol with their approval, ¶¶ 42, 81, 139; Ex.33 at 1982; Ex.42 at 101, *undermining* any inference of fraudulent intent. *See, e.g.*, *Borochoff v. GlaxoSmithKline PLC*, 2008 WL 2073421, *8 (S.D.N.Y. May 9, 2008) ("Allegations of defendants' intent to defraud by suppressing negative data are inconsistent with defendants' disclosure of that data . . . to the FDA."), *aff'd*, 343 F. App'x 671 (2d Cir. 2009).[31]

---

[29] The AC asserts that the Individual Defendants "held themselves out to investors as the employees most knowledgeable on the subject and stated that they had significant visibility into progress on the drug candidate's development," ¶ 137, but identifies only Mr. Soriot's pledge, on behalf of AZ, to "ensure public confidence in the rigorous scientific and regulatory process" for AZD1222's approval, *id.* That statement nowhere purports to identify any particular information provided to Mr. Soriot, let alone contradictory information. Plaintiffs' suggestion that Mr. Soriot's responsibilities under the pledge, shared with eight other CEOs, would have given him access to contradictory information is no different than the insufficient assertions that his high-level position or hands-on management approach demonstrate scienter. *See Nat'l Gen.*, 2021 WL 212337, *10; *see also Tung*, 412 F. Supp. 3d at 460 (allegations of defendant's skill or experience insufficient).

[30] *See In re Carter-Wallace, Inc., Sec. Litig.*, 220 F.3d 36, 41 (2d Cir. 2000) ("[Defendant]'s actual awareness of adverse reports while touting [drug]'s safety does not, on its own, constitute strong circumstantial evidence of conscious misbehavior or recklessness."); *Lehmann*, 2019 WL 4572765, *6 (rejecting knowledge of omitted information as establishing scienter where success of clinical trial was not "out of the realm of possibility"); *Keryx*, 2014 WL 585658, *13 ("[I]t is one thing to suggest that the scientists and analysts did their job poorly; it is another to suggest that the Company knew that they had done their job poorly, and nonetheless (either consciously or recklessly) made statements to hide those errors.").

[31] *See also Philip Morris*, 2021 WL 4135059, *15 (no strong inference of scienter where, *inter alia*, defendants disclosed non-public adverse studies to FDA).

That leaves Plaintiffs' invocation of the "core operations" doctrine—that AZD1222 was an "important and high-profile" drug candidate, and that AZ received $1.2 billion in funding to develop and run a US trial for the vaccine. ¶¶ 137-138. But even putting aside the question of whether this doctrine survived the PSLRA, it does not independently establish scienter. *See Maloney*, 518 F. Supp. 3d at 781-82; *Tung*, 412 F. Supp. 3d at 460 n.3. Moreover, courts have required that "the operation in question constitute nearly all of a company's business before finding scienter," and Plaintiffs must allege that the operation "was essential to [the defendant company's] survival." *Tung*, 412 F. Supp. 3d at 460 n.3; *Thomas v. Shiloh Indus., Inc.*, 2017 WL 1102664, *4 (S.D.N.Y. Mar. 23, 2017). The AC nowhere even attempts such allegations, nor could it given, *inter alia*, that AZ committed to provide AZD1222 at no profit during the pandemic, AZ's annual $26 billion in revenue from its three primary therapy areas during the CP, and the extensive products and pipelines in each. *See supra* at 3.

At bottom, the AC's own allegations and undisputed public record preclude any "cogent" inference of scienter, let alone one that is "at least as compelling as" one of non-fraudulent intent:

- AZ partnered with Oxford, world-leading vaccinology experts who had already been working on a COVID-19 vaccine that used a "tried and tested" approach, ¶¶ 29, 31-32;

- AZ continued to partner with Oxford throughout, with Oxford leading most of the ex-US trials and making virtually identical disclosures at almost every step, ¶¶ 38, 40-41, 47, 51; *e.g.*, Ex.5; Ex.7; Ex.10; Ex.13; Ex.21; Ex.27; Ex.32; Ex.35; Ex.63.

- The trials were conducted with transparency and care, with details disclosed up front and throughout; regulator notification and approval of protocol amendments based on ongoing developments; pauses for independent review of potential safety issues; and results announced in granular detail and published for peer-review, ¶¶ 38, 42, 47, 49-54, 57, 65, 72, 76, 78-79, 81, 101-104, 139; *supra* 4-13;

- The vaccine was successfully developed, at record speed, as confirmed by authorizations and approvals around the world, including during the CP, ¶¶ 23, 115, 119-20; *supra* 13; and

- The vaccine was manufactured and distributed, again at record speed and under unprecedented conditions, with the vaccine currently used in over 170 countries, and in

particular in low- and middle-income countries, ¶¶ 38, 39, 44, 57; *supra* 14.[32]

Nothing alleged in the AC remotely suggests fraud, but rather a company stepping up to help ensure the fair and equitable distribution of a COVID-19 vaccine during a worldwide pandemic—at no profit, and undertaking manufacturing costs at risk should authorizations or approvals not come.

C. The AC Fails to Plead Loss Causation

Plaintiffs' failure to plead loss causation provides an independent dismissal ground. Loss causation is the "causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172 (2d Cir. 2005). Plaintiffs must plead facts showing that an "alleged misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *Boluka Garment Co., Ltd. v. Canaan Inc.*, 2021 WL 2853284, *3 (S.D.N.Y. July 8, 2021). Where, as here, plaintiffs pursue a "corrective disclosure" theory, ¶¶ 141-142, the corrective disclosure must "reveal to the market some part of the truth regarding the alleged fraud," and "disclose the information that the complaint describes" as having previously been concealed, *Boluka*, 2021 WL 2853284, *3-4; *see also In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 511 (2d Cir. 2010).

None of the disclosures to which Plaintiffs point is "corrective."

November 23–25, 2020 Disclosures. AZ's November 23 release announcing high-level results from an interim analysis of COV0002 and COV003—including that the vaccine met its primary efficacy endpoint—and certain press and analyst reports raising questions about the results that followed over the next two days, ¶¶ 78-92, do not constitute corrective disclosures. None revealed any negative facts previously withheld or, more importantly, exposed any prior statement as

[32] Furthermore, that a pharmaceutical company would invest time and resources, and risk its reputation with regulators and customers—and here, at no profit—to develop a product it believed would not work and through clinical trials it believed were flawed is not plausible. *See Gillis*, 197 F. Supp. 3d at 600; *In re GeoPharma, Inc. Sec. Litig.*, 411 F. Supp. 2d 434, 446-47 (S.D.N.Y. 2006); *Davidoff v. Farina*, 2005 WL 2030501, *11 n.19 (S.D.N.Y. Aug. 22, 2005).

misleading: any news regarding trials being conducted in multiple countries, in different age ranges, with different controls, and at various doses had already been disclosed to the market. *See supra* at 4-10, 23-24. The AC nowhere explains, for example, how additional detail regarding the genesis of the already-disclosed two dosing regimens somehow revealed prior fraud, particularly when both regimens undisputedly demonstrated efficacy. *See Nguyen v. New Link Genetics Corp.*, 2019 WL 591556, *7-8 (S.D.N.Y. Feb. 13, 2019) (loss causation not alleged where alleged corrective disclosure "did nothing to reveal the truth behind the alleged fraud").[33] Moreover, neither "negative journalistic characterization of previously disclosed facts," nor press or analyst speculation constitute corrective disclosures. *See Omnicom,* 597 F.3d at 512.[34]

December 14, 2020 Article. Plaintiffs' claim of a corrective disclosure on December 14 is even weaker, with Dr. Pangalos expressing the unremarkable opinion that AZ "would have run the study a little bit differently if we had been doing it from scratch," ¶ 114, and confirming his view that "the Oxford group have done a fantastic job," Ex.48. The AC nowhere explains how this revealed anything, much less some prior alleged fraud. And while the AC references the Alexion acquisition in an unsuccessful bid to allege motive, ¶ 140, its loss causation allegations ignore that the transaction was announced on Saturday, December 12, Ex.47. The AC makes no effort to address market reaction to that separate announcement, *see, e.g.*, Ex.49; Ex.50, and thus to "disaggregate those losses caused by the [unrelated events] from disclosures of the truth behind the alleged misstatements," *City of Westmoreland Police & Fire Ret. Sys. v. MetLife, Inc.*, 129 F. Supp. 3d 48, 85 (S.D.N.Y. 2015).[35]

January 26–29, 2021 Disclosures. That leaves Plaintiffs with their weakest attempt, looking to

[33] *Accord In re Magnum Hunter Res. Corp. Sec. Litig.*, 26. F. Supp. 3d 278, 299-300 (S.D.N.Y. 2014), *aff'd*, 616 F. App'x 442 (2d Cir. 2015); *Kuriakose v. Fed. Home Loan Mortg. Corp.*, 897 F. Supp. 2d 168, 177 (S.D.N.Y. 2012), *aff'd*, 543 F. App'x 72 (2d Cir. 2013).

[34] *Accord Lau v. Opera Ltd.*, 2021 WL 964642, *12 (S.D.N.Y. Mar. 13, 2021); *Fila v. Pingtan Marine Enter.*, 195 F. Supp. 3d 489, 497 (S.D.N.Y. 2016); *Janbay v. Canadian Solar, Inc.,* 2012 WL 1080306, *16 (S.D.N.Y. Mar. 30, 2012).

[35] *See also Cent. States, Se. & Sw. Areas Pension Fund v. Fed. Home Loan Mortg. Corp.*, 543 F. App'x 72, 76 (2d Cir. 2013); *In re Frontier Commc'ns Corp. S'holders Litig.*, 2019 WL 1099075, *24 (D. Conn. Mar. 8, 2019).

seize upon a stock price decline over four days in January 2021, ¶¶ 118-123, by cobbling together an assortment of disclosures that nowhere revealed prior fraud:

- On January 26, German press quoted unnamed government sources claiming, without support, that the vaccine was less than 10% effective for people 65+, which assertion was rejected by German health ministry officials, ¶¶ 118-119;

- On January 28, Germany's vaccine commission recommended use of the vaccine for persons 18-64, ¶ 119;

- On January 29, France's President questioned effectiveness for those 65+, but acknowledged he had no figures or official information, ¶ 122; Ex.55;

- Also on January 29, a CHMP assessment noted the limited number of COVID-19 cases among subjects 55+, but recommended CMA for *all* adults 18+, which was granted, ¶¶ 120-121; Ex.53; Ex.54 at 171-72, 174.

As Plaintiffs' own allegations demonstrate, analyses of AZD1222's clinical trial methodology and efficacy had been widely published and circulated well before late January 2021. Whatever predictions of future approvals were proffered, governments had already begun approving the vaccine for emergency use based on the same results. *See supra* at 13. And yet more idle speculation and commentary on already-disclosed information again revealed nothing new to investors.[36]

POINT II: THE AC FAILS TO PLEAD A SECTION 20 CLAIM

Without a primary securities law violation, the AC fails to plead control person liability under Section 20(a). *See Tung*, 412 F. Supp. 3d at 462.

POINT III: THE CLAIMS AGAINST MR. DUNOYER SUFFER FURTHER DEFECTS

The claims against Mr. Dunoyer must be dismissed for yet additional reasons, beyond those above. *First*, Mr. Dunoyer is not alleged to have made any false statement. As such, he can have no liability under Section 10(b). *See Janus Cap. Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 141 (2011);

[36] To the extent Plaintiffs allege that share price declined because Germany temporarily withheld approval for those 65+, that regulatory development corrected no prior untruth. *See Biovail*, 615 F. Supp. 2d at 229 (decline following failure to gain FDA approval "was caused by the agency's failure to approve the drug—not by any 'corrective' disclosure of some prior untruth"). German regulators approved AZD1222 for those 65+ within three months, on March 4, 2021. Ex.58.

In re UBS AG Sec. Litig., 2012 WL 4471265, *9-11 (S.D.N.Y. Sept. 28, 2012), *aff'd*, 752 F.3d 173 (2d Cir. 2014). *Second,* the AC fails to plead his "control" and "culpable participation," for Section 20(a) liability. "Control" requires both "actual control over the primary violator" and "actual control over the *transaction* in question." *In re NQ Mobile, Inc. Sec. Litig.*, 2015 WL 1501461, *2 (S.D.N.Y. Mar. 27, 2015). Officer status alone is insufficient. *In re Global Crossing, Ltd. Sec. Litig.*, 2005 WL 1907005, *12 (S.D.N.Y. Aug. 8, 2005). The AC is bereft of any allegation regarding Mr. Dunoyer's control other than conclusory labels, ¶¶ 157-158, which are insufficient, *Global Crossing*, 2005 WL 1907005, *12. The AC's failure is not surprising, as Mr. Dunoyer was AZ's CFO during the CP, ¶ 16, whereas the challenged statements relate to AZD1222 and clinical trials. Nor does the AC plead any facts, let alone particularized facts, regarding his conduct or state of mind, and thus fails to allege culpable participation. *NQ Mobile*, 2015 WL 1501461, *3-4; *Global Crossing*, 2005 WL 1501461, *12. These failures separately require dismissal.

CONCLUSION

For the foregoing reasons, the AC should be dismissed with prejudice.

Dated: New York, New York
September 27, 2021

Respectfully submitted,

FRESHFIELDS BRUCKHAUS DERINGER US LLP

/s/ Meredith Kotler

Meredith Kotler
Mary Eaton
Marques S. Tracy
Adam M. Rosenfeld
601 Lexington Avenue, 31st Floor
New York, New York 10022
Telephone: (212) 277-4000
meredith.kotler@freshfields.com
mary.eaton@freshfields.com
marques.tracy@freshfields.com
adam.rosenfeld@freshfields.com

Attorneys for Defendants